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Original Article

Cuffed vs. uncuffed tracheal tubes in children: a randomised controlled trial comparing leak, tidal volume and complications

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Summary

Cuffed tracheal tubes are increasingly used in paediatric anaesthetic practice. This study compared tidal volume and leakage around cuffed and uncuffed tracheal tubes in children who required standardised mechanical ventilation of their lungs in the operating theatre. Children (0–16 years) undergoing elective surgery requiring tracheal intubation were randomly assigned to receive either a cuffed or an uncuffed tracheal tube. Assessments were made at five different time-points: during volume-controlled ventilation 6 $ml.kg^{-1}$, PEEP 5 cmH_2O and during pressure-controlled ventilation 10 cmH_2O / PEEP 5 cmH_2O. The pressure-controlled ventilation measurement time-points were: just before a standardised recruitment manoeuvre; just after recruitment manoeuvre; 10 min; and 30 min after the recruitment manoeuvre. Problems and complications were recorded. During volume-controlled ventilation, leakage was significantly less with cuffed tracheal tubes than with uncuffed tracheal tubes; in $ml.kg^{-1}$, median (IQR [range]) 0.20 (0.13–0.39 [0.04–0.60]) vs. 0.82 (0.58–1.38 [0.24–4.85]), respectively, $p < 0.001$. With pressure-controlled ventilation, leakage was less with cuffed tracheal tubes and stayed unchanged over a 30-min period, whereas with uncuffed tracheal tubes, leakage was higher and increased further over the 30-min period. Tidal volumes were higher in the cuffed group and increased over time, but in the uncuffed group were lower and decreased over time. Both groups showed an increase in tidal volumes following recruitment manoeuvres. There were more short-term complications with uncuffed tracheal tubes, but no major complications were recorded in either group at long-term follow-up. With standardised ventilator settings, cuffed tracheal tubes produced better ventilation characteristics compared with uncuffed tracheal tubes during general anaesthesia for routine elective surgery.

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Introduction

Children's tracheas have traditionally been intubated with uncuffed tracheal tubes (TT) due to differences between adult and paediatric subglottic anatomy, and fears that cuffs may lead to mucosal damage and subglottic stenosis. Despite this, cuffed TTs are increasingly used in paediatric anaesthesia. Over the last 20 years, evidence suggests that cuffed TT may have advantages over uncuffed, and are associated with at least similar, if not superior, airway outcomes when compared with uncuffed TT in children [1–5]. Some of these studies were performed in an intensive care setting where intubation and ventilation were carried out for prolonged periods [3], but were of an observational nature. Others were randomised studies that looked at children as a single group in an anaesthetic setting rather than dividing them into specific age groups [4]. The largest and latest randomised controlled study by Weiss et al. [1] included sub-group analysis of small infants in an anaesthetic setting, and demonstrated that cuffed TT did not have worse outcomes than uncuffed, and were associated with fewer insertion attempts. Other studies have referred to clinical, environmental and economic benefits of cuffed tubes.

This study is the first randomised controlled trial to compare leakage and tidal volumes in cuffed vs. uncuffed TT in the operating theatre in children during standardised mechanical ventilation.

Methods

This trial was conducted as a single-centre, randomised, parallel-group study at Princess Margaret Hospital for Children in Perth, Western Australia. It is the only tertiary referral paediatric centre in Western Australia, with approximately 14,000 anaesthetics administered every year. Approval for this study was obtained from the Princess Margaret Hospital for Children Ethics Committee and the University of Western Australia Committee.

Recruitment was carried out between 3 February 2012 and 30 January 2014 through the Department of Anaesthesia and Pain Management. Written informed consent was obtained from parents (with assent from children whenever possible) before enrolment. Recruited children were randomly assigned to one of two groups in a 1:1 ratio to receive either a cuffed or uncuffed TT for airway management. No interim analyses for efficacy or futility were performed, and an independent data monitoring committee was set up.

All children aged 0–16 years weighing more than > 5 kg and undergoing elective surgery were considered. Patients with airway malformation, upper airway surgery, contra-indications to either cuffed or uncuffed tubes, or requirement for postoperative ventilation, were not studied.

Subjects were recruited into the trial during anaesthetic pre-operative assessment. Following recruitment, children were randomly assigned by computer-generated block randomisation to either a 'cuffed TT' or 'uncuffed TT' group in equal numbers. Withdrawals from the study were not replaced. Preschool children (< 6 years) and school children ≥ 6 years) were analysed both separately and together.

All children were anaesthetised in accordance with the safety standards of the Australian and New Zealand College of Anaesthetists (ANZCA) and the Department of Anaesthesia and Pain Management, Princess Margaret Hospital for Children in Perth, Australia. Induction and maintenance of anaesthesia was performed as deemed appropriate by the attending anaesthetist (who was independent of the study team) with either inhalational sevoflurane (up to 8 vol%) or intravenous (i.v.) propofol (3–5 $mg.kg^{-1}$). Oral tracheal intubation was performed as per the attending anaesthetist's usual practice, with neuromuscular blocking drugs optional. Standard institutional TTs (Table 1) and Draeger Primus anaesthesia workstations (Drägerwerk AG & Co. KGaA, Luebeck, Germany) were used. Cuffed TTs < size 5 had low-volume cuffs (Microcuff, Halyard Health Inc., Atlanta, GA, USA), and those size 5 and above had high-volume low-pressure cuffs (Mallinckrodt Medical, Athlone, Ireland). Routine anaesthetic monitoring and continuous cuff manometry (Portex Limited, Hythe, Kent, UK) was used for cuffed TTs, with cuff pressures monitored continuously. Following inflation of the TT cuff, pressure was measured, and if necessary adjusted to pressures ≤ 20 cmH_2O to allow for a good cuff seal without hyperinflation.

Initial tube size was based on the type of tube and age of patient (Table 2). Final tube size was decided by the attending anaesthetist, and was based on the

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Table 1 Brand and manufacturer details of tracheal tubes (TT). Size is internal diameter in mm.

Size	Manufacturer
Cuffed TT	
3.5–4.5	Kimberly Clark KimVent Microcuff
5.0–7.5	Smith Portex
8.0	Mallinckrodt
8.5	Mallinckrodt/Smith Portex
Uncuffed TT	
2.0–2.5	Unomedical UC
3.0–7.5	Mallinckrodt Contour Murphy Eye
7.5–8.5	Smith Portex

absence of resistance to insertion of the tube and the presence of audible leak (with inflation pressures of 25 cmH_2O following initial cuff deflation). As necessary, TT sizes were adjusted up or down by half a size to achieve these conditions.

Measurements were carried out under both volume-controlled ventilation (VCV) and pressure-controlled ventilation (PCV). Ventilation was set initially to VCV of 6 $ml.kg^{-1}$ and PEEP 5 cmH_2O. Five anaesthesia workstation measurements of inspiratory and expiratory tidal volumes were recorded, and the mean taken for analysis of leakage around the TT. Ventilation was then adjusted to PCV of 10 cmH_2O, PEEP of 5 cmH_2O and leakage around the tube analysed again in the same way.

Following these measurements, a standardised recruitment manoeuvre was performed by giving 10 slow manual breaths up to 35 cmH_2O, followed by PEEP of 5 cmH_2O [6]. Following the recruitment manoeuvre, repeat measurements were recorded immediately, then again at 10 min and 20 min. Once these measurements were taken, ventilation was at the discretion of the anaesthetist for the remainder of the case.

Table 2 Initial tracheal tube (TT) sizes (internal diameter in mm), by age.

Age	Cuffed TT	Uncuffed TT
< 8 months	3.0	3.5
8 months–< 18 months	3.5	4.0
18 months–< 36 months	4.0	4.5
36 months–< 5 years	4.5	5.0
5 years and older	Age/4 + 3.5	Age/4 + 4

Respiratory rate and inspiratory times were standardised according to age (Table 3). In both groups, the TT was removed at the discretion of the attending anaesthetist, and timing of extubation recorded.

All patients were transported in the lateral position to the recovery unit after ensuring that their airway, air exchange and oxygenation were adequate. Oxygen saturation was measured continuously until discharge from the recovery unit.

Oxygen saturation was recorded when the subjects were calm and the pulse oximeter showed consistent detection. Lowest measured SpO_2 values were recorded 10 min before removal of the TT, and at 1 min, 2 min, 3 min, 5 min, 7 min, 10 min, 15 min, 20 min, 25 min and 30 min after removal.

Any respiratory adverse events (laryngospasm; bronchospasm; desaturation < 95%; airway obstruction; severe coughing and/or postoperative stridor) as well as subsequent interventions were recorded. We also recorded risk factors for peri-operative respiratory adverse events [7], together with baseline characteristics. All families were interviewed on the ward pre-discharge regarding the presence or absence of sore throat (if patient > 3 years) or other respiratory adverse events. In line with institutional ethics regulations, we monitored patients for 3 years following the last patient recruitment to identify if any participants required subsequent airway intervention.

The primary end-point for the study was leakage around the TT, defined as the difference between inspiratory and expiratory tidal volumes (as measured by the anaesthesia workstation) at five different time-points before the start of surgery. Secondary end-points were: inspiratory tidal volume; expiratory tidal volume; number of attempts to insert and correctly size the tracheal tube; adverse events; sore throat in children old enough to report (3 years and above) and hoarse voice.

Table 3 Ventilation settings according to age.

Age; y	Ventilation settings
< 1	RR 33 $breaths.min^{-1}$: IT 0.6 s
1–6	RR 30 $breaths.min^{-1}$: IT 0.8 s
7–16	RR 25 $breaths.min^{-1}$: IT 0.9 s

RR, respiratory rate; IT, inspiratory time.

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In pilot studies on children at our institution, we observed differences in mean TT-leak between cuffed TT (0.5 $ml.kg^{-1}$) and uncuffed TT (0.65 $ml.kg^{-1}$). Based on our data and assuming a common standard deviation of 0.23, a sample size of 52 children per group would provide 90% power to detect a difference in leakage of 0.15 $ml.kg^{-1}$ between study groups. We analysed leakage between the two groups using Mann–Whitney's test and a significance level of 0.05.

For the secondary end-points, unadjusted analysis was performed with binary logistic regression.

Results

One-hundred and four children between 0 and 16 years of age were recruited (Fig. 1, Table 4).

Fifty-two patients were aged < 6 years and 52 patients aged 6–16 years. Twenty-six patients in each age group were included in the 'cuffed TT group' and 26 in the 'uncuffed TT group'. In the uncuffed group, data from six (< 6 years) and 12 (6–12 years) subjects could not be collected due to tube-related problems (e.g. leak too large). Long-term follow-up data ranged from 3 to 5 years after surgery. Table 4 depicts the baseline characteristics for subjects in both cuffed and uncuffed TT groups. In the uncuffed group, one child who was under the weight limit of 5 kg (3.8 kg) was recruited by mistake, but the child's data were included in the analysis. Table 4 includes the usage of neuromuscular blockade in all groups.

Tables 5, 6 and 7 show leakage (inspired – expired tidal volume) at the time-point, < 6 and 6–16 years groups, respectively.

Table 8 shows the number of attempts and problems encountered at intubation. In the cuffed TT group, about 80% were successfully intubated with a correctly-sized TT at first attempt compared with only about 30% in the uncuffed group. There were fewer corrective interventions in the cuffed group. Tube size required changing in around 10% in the cuffed group and 30% in the uncuffed group. A change in tube type

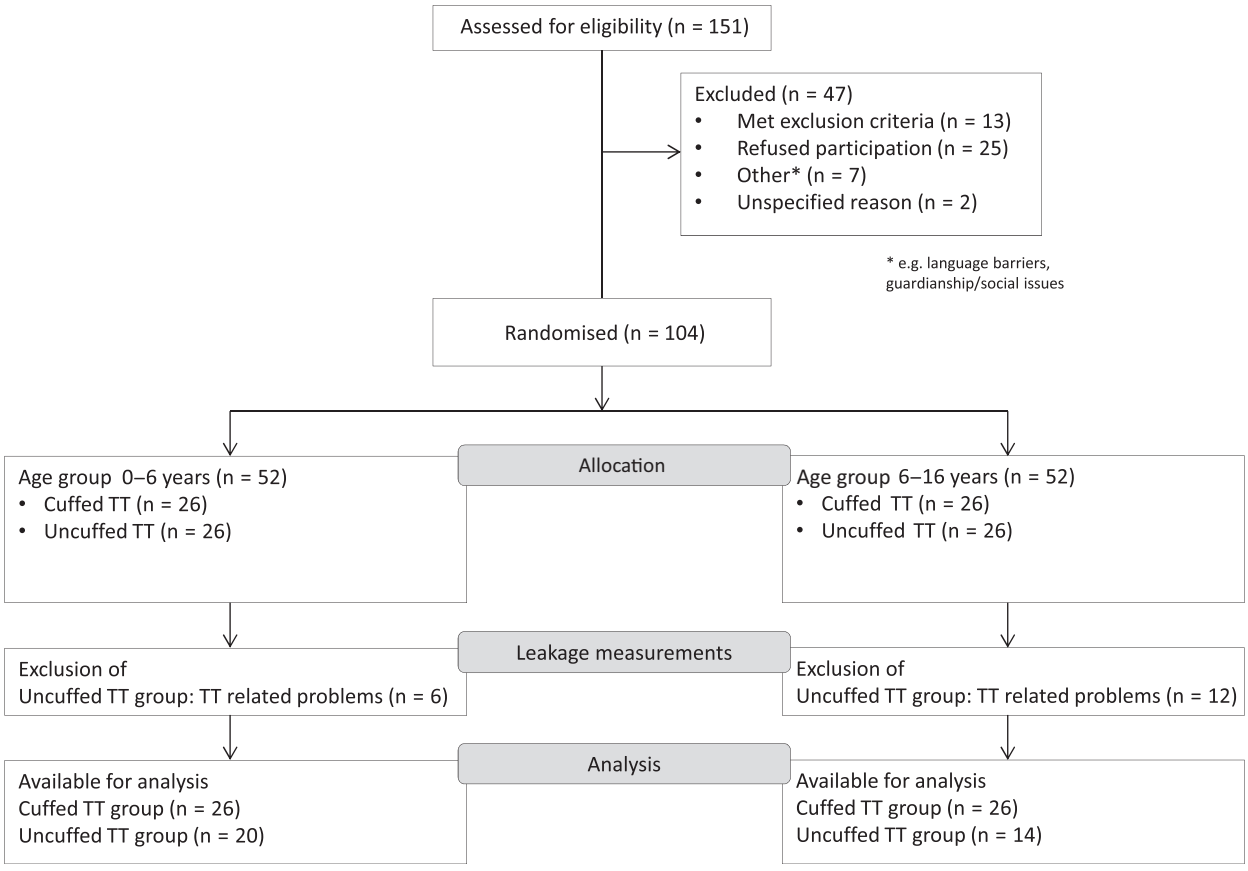

Figure 1 CONSORT diagram. TT, tracheal tube.

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Table 4 Baseline characteristics, ASA status, use of neuromuscular blockade and risk factor distribution for respiratory adverse events. Values are mean (SD), median (IQR [range]) or number (proportion).

	Groups (age range, tracheal tube type)					
	All		< 6 years		6–16 years	
	Cuffed	Uncuffed	Cuffed	Uncuffed	Cuffed	Uncuffed
n	52	34	26	20	26	14
Male; n	37 (71.2)	16 (47.1)	18 (69.2)	10 (50)	19 (73.1)	6 (42.9)
Age; years	6.0 (1.1–9.2 [0.1–14.9])	4.0 (1.0–7.5 [0.2–15.2])	1.1 (0.8–2.8 [0.1–6.0])	1.2 (0.7–2.5 [0.2–5.6])	9.2 (7.3–13.2 [6.0–14.9])	8.7 (7.1–10.2 [6.0–15.2])
Weight; kg	18.4 (11.1–36.4 [5.6–116])	14.1 (9.8–27.7 [3.8–65.8])	11.1 (8.9–13.5 [5.6–24.5])	10.5 (6.8–13.1 [3.8–22.9])	36.4 (22.8–55.0 [14.1–116.0])	28.6 (20.0–32.0 [12.7–65.8])
ASA physical status						
1	21 (40.4%)	13 (38.2%)	5 (19.2%)	6 (30.0%)	16 (61.5%)	7 (50.0%)
2	24 (46.2%)	18 (52.9%)	18 (69.2%)	13 (65.0%)	6 (23.1%)	5 (35.7%)
3	7 (13.5%)	3 (8.8%)	3 (11.5%)	1 (5.0%)	4 (15.4%)	2 (14.3%)
Neuromuscular blockade; Y	27 (52%)	17 (50%)	13 (50%)	9 (45%)	14 (54%)	8 (57%)
Current/recent upper respiratory tract infection	11 (21.2%)	11 (32.4%)	8 (30.8%)	10 (50.0%)	3 (11.5%)	1 (7.1%)
Wheeze	4 (7.7%)	5 (14.7%)	3 (11.5%)	3 (15.0%)	1 (3.8%)	2 (14.3%)
Wheeze on exercise	1 (1.9%)	2 (5.9%)	-	1 (5.0%)	1 (3.8%)	1 (7.1%)
Dry night cough	9 (17.3%)	7 (20.6%)	5 (19.2%)	4 (20.0%)	4 (15.4%)	3 (21.4%)
Current eczema	5 (9.6%)	4 (11.8%)	4 (15.4%)	3 (15.0%)	1 (3.8%)	1 (7.1%)
Past eczema	8 (15.4%)	3 (8.8%)	4 (15.4%)	2 (10.0%)	4 (15.4%)	1 (7.1%)
Family history						
Asthma	21 (40.4%)	9 (26.5%)	11 (42.3%)	6 (30.0%)	10 (38.5%)	3 (21.4%)
Eczema	18 (34.6%)	7 (20.6%)	8 (30.8%)	6 (30.0%)	10 (38.5%)	1 (7.1%)
Hay fever	23 (44.2%)	11 (32.4%)	12 (46.2%)	4 (20.0%)	11 (42.3%)	7 (50.0%)
Passive smoking	15 (28.8%)	7 (20.6%)	8 (30.8%)	3 (15.0%)	7 (26.9%)	4 (28.6%)

Table 5 Tracheal tube (TT) leak, inspired and expired tidal volume in the cuffed vs. uncuffed groups, independent of age. Values are median (IQR [range]).

	Cuffed TT n = 52	Uncuffed TT n = 34	p value	U
Leakage volume; ml.kg^{-1}				
VCV	0.20 (0.13–0.39 [0.04–0.60])	0.92 (0.58–1.38 [0.24–4.85])	< 0.001	99.5
PCV pre-recruitment	0.21 (0.14–0.36 [0.04–0.57])	1.25 (0.65–2.48 [0.26–6.07])	< 0.001	36.0
PCV post-recruitment	0.21 (0.16–0.33 [0.07–0.61])	1.00 (0.57–2.10 [0.21–5.39])	< 0.001	65.0
PCV 10 min post-recruitment	0.23 (0.18–0.33 [0.03–0.64])	1.55 (0.75–2.52 [0.50–6.17])	< 0.001	5.5
PCV 30 min post-recruitment	0.24 (0.18–0.31 [0.11–0.63])	1.78 (1.05–2.77 [0.67–6.23])	< 0.001	0.0
Inspiratory tidal volume; ml.kg^{-1}				
VCV	6.46 (6.16–6.64 [5.26–7.33])	6.28 (6.10–6.61 [5.71–7.62])	0.382	785.0
PCV pre-recruitment	6.83 (6.24–7.60 [4.24–10.25])	6.51 (5.68–7.31 [4.60–9.01])	0.044	655.5
PCV post-recruitment	7.46 (6.75–8.34 [5.57–10.99])	7.13 (6.32–7.81 [5.36–9.08])	0.131	713.0
PCV 10 min post-recruitment	7.39 (6.76–8.34 [5.55–11.05])	6.61 (5.86–7.48 [4.04–8.69])	0.001	516.0
PCV 30 min post-recruitment	7.40 (6.73–8.22 [5.48–10.95])	6.09 (5.34–7.11 [3.88–8.12])	< 0.001	335.0
Expiratory tidal volume; ml.kg^{-1}				
VCV	6.10 (5.84–6.47 [5.11–7.20])	5.48 (4.89–5.85 [1.20–6.93])	< 0.001	343.0
PCV pre-recruitment	6.65 (6.04–7.37 [4.03–10.17])	4.76 (4.04–5.76 [2.21–6.97])	< 0.001	193.0
PCV post-recruitment	7.25 (6.48–8.05 [5.41–10.80])	5.64 (4.83–6.75 [3.16–7.86])	< 0.001	293.0
PCV 10 min post-recruitment	7.13 (6.56–8.03 [5.37–10.82])	4.94 (3.38–5.83 [1.77–7.35])	< 0.001	137.0
PCV 30 min post-recruitment	7.16 (6.50–7.96 [5.33–10.63])	4.02 (2.83–5.10 [1.26–6.70])	< 0.001	53.0

VCV, volume-controlled ventilation; PCV, pressure-controlled ventilation.

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Table 6 Tracheal tube (TT) leak (ml.kg^{-1}) inspired and expired tidal volume in the < 6 years group. Values are median (IQR [range]).

	Cuffed TT n = 26	Uncuffed TT n = 20	p value	U
Leakage volume; ml.kg^{-1}				
VCV	0.2 (0.13–0.38 [0.04–0.59])	0.82 (0.53–1.45 [0.24–4.85])	< 0.001	36.5
PCV pre-recruitment	0.18 (0.14–0.35 [0.04–0.44])	1.01 (0.58–2.22 [0.26–6.07])	< 0.001	16.0
PCV post-recruitment	0.2 (0.16–0.33 [0.08–0.41])	0.8 (0.50–1.94 [0.21–5.39])	< 0.001	21.0
PCV 10 m post-recruitment	0.25 (0.18–0.32 [0.03–0.45])	1.37 (0.68–2.25 [0.50–6.17])	< 0.001	0.0
PCV 30 m post-recruitment	0.24 (0.20–0.30 [0.11–0.43])	1.55 (0.95–2.31 [0.67–6.23])	< 0.001	0.0
Inspiratory tidal volume; ml.kg^{-1}				
VCV	6.57 (6.45–6.80 [5.26–7.33])	6.55 (6.17–6.74 [5.81–7.62])	0.451	226.0
PCV pre-recruitment	6.83 (6.46–7.51 [5.89–8.33])	6.56 (5.26–7.45 [4.60–9.01])	0.144	194.0
PCV post-recruitment	7.5 (7.00–8.40 [6.12–9.39])	7.12 (6.81–7.83 [5.36–9.08])	0.191	201.0
PCV 10 min post-recruitment	7.48 (7.04–8.46 [6.01–9.23])	6.76 (5.77–7.39 [4.04–8.69])	0.004	129.0
PCV 30 min post-recruitment	7.49 (6.96–8.38 [5.88–9.29])	6.09 (5.31–6.97 [3.88–8.12])	< 0.001	69.0
Expiratory tidal volume; ml.kg^{-1}				
VCV	6.29 (6.02–6.65 [5.11–7.2])	5.67 (4.56–6.24 [1.2–6.93])	0.001	115.0
PCV pre-recruitment	6.65 (6.09–7.21 [5.72–7.93])	4.79 (3.99–6.17 [2.73–6.97])	< 0.001	63
PCV post-recruitment	7.36 (6.71–8.16 [5.96–9.14])	6.26 (5.08–7.01 [3.16–7.31])	< 0.001	87
PCV 10 min post-recruitment	7.25 (6.86–8.13 [5.79–9.09])	5.15 (3.38–6.09 [1.98–7.34])	< 0.001	28
PCV 30 min post-recruitment	7.21 (6.71–8.08 [5.72–9.03])	4.11 (3.03–5.40 [1.61–6.57])	< 0.001	13

VCV, volume-controlled ventilation; PCV, pressure-controlled ventilation.

Table 7 Tracheal tube (TT) leak (ml.kg^{-1}), inspired and expired tidal volume in the 6–16-year old group. Values are median (IQR [range]).

	Cuffed TT n = 26	Uncuffed TT n = 14	p value	U
Leakage volume; ml.kg^{-1}				
VCV	0.20 (0.12–0.40 [0.04–0.60])	0.93 (0.75–1.28 [0.41–3.53])	< 0.001	11.0
PCV pre-recruitment	0.23 (0.15–0.37 [0.05–0.57])	1.43 (1.11–2.87 [0.54–4.39])	< 0.001	1.0
PCV post-recruitment	0.22 (0.17–0.34 [0.07–0.61])	1.16 (0.77–2.54 [0.51–4.15])	< 0.001	5.0
PCV 10 min post-recruitment	0.23 (0.18–0.35 [0.11–0.64])	1.81 (1.06–3.50 [0.73–5.56])	< 0.001	0.0
PCV 30 min post-recruitment	0.24 (0.16–0.40 [0.12–0.63])	1.99 (1.39–3.74 [0.75–5.64])	< 0.001	0.0
Inspiratory tidal volumes; ml.kg^{-1}				
VCV	6.20 (6.08–6.46 [5.80–6.89])	6.18 (6.09–6.26 [5.71–6.48])	0.411	153.0
PCV pre-recruitment	6.82 (6.07–7.76 [4.24–10.25])	6.45 (5.74–7.08 [5.40–7.57])	0.223	139.0
PCV post-recruitment	7.27 (6.50–7.98 [5.57–10.99])	7.13 (6.13–7.75 [5.42–8.76])	0.294	145.0
PCV 10 min post-recruitment	7.27 (6.49–7.99 [5.55–11.05])	6.51 (5.88–7.48 [4.91–8.46])	0.070	118.0
PCV 30 min post-recruitment	7.25 (6.55–7.99 [5.48–10.95])	6.09 (5.34–7.11 [4.64–8.06])	0.010	92.0
Expiratory tidal volumes; ml.kg^{-1}				
VCV	5.92 (5.78–6.14 [5.46–6.58])	5.15 (4.96–5.42 [2.18–6.07])	< 0.001	30
PCV pre-recruitment	6.63 (5.80–7.56 [4.03–10.17])	4.76 (4.27–5.21 [2.29–6.05])	< 0.001	29
PCV post-recruitment	7.07 (6.29–7.61 [5.41–10.80])	5.21 (4.53–6.26 [3.65–7.86])	< 0.001	45
PCV 10 min post-recruitment	7.04 (6.26–7.61 [5.37–10.82])	3.96 (3.38–5.52 [2.9–7.35])	< 0.001	30
PCV 30 min post-recruitment	7.02 (6.30–7.54 [5.33–10.63])	3.45 (2.43–4.75 [2.26–6.7])	< 0.001	12

VCV, volume-controlled ventilation; PCV, pressure-controlled ventilation.

was only required in the uncuffed group (i.e. changed to cuffed).

The incidence of some complications was low, making meaningful analysis difficult, but overall there were fewer in the cuffed group (Tables 8 and 9).

Discussion

Our study compared specific clinical end-points in cuffed TT vs. uncuffed TT groups during two alternative ventilation strategies. Cuffed TTs provided not only better ventilation and maintenance of respiratory

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Table 8 Number of tracheal tube insertions and problems encountered in both age groups. Values are number (proportion).

	All		< 6 years		6–16 years	
	Cuffed n = 52	Uncuffed	Cuffed n = 26	Uncuffed	Cuffed n = 26	Uncuffed
Insertions						
1	43 (82.7%)	17 (32.7%)	22 (84.6%)	11 (42.3%)	21 (80.8%)	6 (23.1%)
2	8 (15.4%)	23 (44.2%)	4 (15.4%)	11 (42.3%)	4 (15.4%)	12 (46.2%)
> 2	1 (1.9%)	12 (23.1%)	0	4 (15.4%)	1 (3.8%)	8 (30.8%)
Size change	6 (11.5%)	17 (32.7%)	3 (11.5%)	9 (34.6%)	3 (11.5%)	8 (30.8%)
Type change (cuffed ⇔ uncuffed)	0	13 (25%)	0	4 (15.4%)	0	9 (34.6%)
Throat pack (leak)	0	4 (7.7%)	0	1 (3.8%)	0	3 (11.5%)
Excessive leak, only manual ventilation possible (leak)	0	1 (1.9%)	0	1 (3.8%)	0	0
Inspiratory pressure increased (to reach acceptable tidal volume)	0	8 (15.4%)	0	5 (19.2%)	0	3 (11.5%)

Table 9 Peri-operative and postoperative respiratory complications for all patients by cuffed/ uncuffed groups. Values number (proportion). TT, tracheal tube.

	Cuffed TT n = 52	Uncuffed TT n = 52	p value	Odds ratio (95%CI)
Peri-operative respiratory adverse events				
Laryngospasm	0	2 (5.9%)	–	–
Bronchospasm	0	1 (2.9%)	–	–
Severe persistent coughing	5 (9.6%)	13 (38.2%)	0.003	5.8 (1.8–18.4)
Desaturation < 95%	8 (15.4%)	11 (32.4%)	0.069	2.6 (0.9–7.5)
Airway obstruction	1 (1.9%)	0	–	–
Stridor	0	0	–	–
Any of above	10 (19.2%)	18 (52.9)	0.002	4.7 (1.8–12.4)
Follow-up complications post-surgery				
Sore throat	4 (7.7%)	11 (33.3%)	0.005	6.0 (1.7–21.0)
Hoarse voice	5 (9.6%)	9 (26.5%)	0.046	3.4 (1.0–11.2)

mechanics, but also had lower requirements for corrective measures at intubation and a lower rate of adverse events in children whose tracheas were intubated for elective surgery, as compared with uncuffed TTs.

The leak measurements in this study consisted of both inspiratory and expiratory components, but did not distinguish between the two, assuming the majority of the leak to be inspiratory because of the higher intra-tracheal pressure. The leak around the TT was significantly lower in the cuffed TT group at every single assessment point. During PCV, the leak remained relatively unchanged in the cuffed TT group over the four measurement points, but in the uncuffed TT group the leak decreased slightly after the recruitment manoeuvre, then increased significantly over time in both age groups. This suggests that recruitment manoeuvres may be required less often in children with cuffed TTs.

All tidal volume measurements were higher in the cuffed TT group at every assessment point, with the difference increasing at the later points. Inspired tidal volume measurements reflect both leak and expired tidal volume components, and thus expired tidal volumes more accurately reflect actual tidal volume, notwithstanding the possibility of an unmeasured expiratory leak. Expired tidal volume initially increased after the recruitment manoeuvre in both TT groups and both age groups, demonstrating the positive effects of recruitment on tidal volume as expected. Expired tidal volume increased over time in the cuffed group,

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but decreased in the uncuffed TT group. These findings suggest that there is superior maintenance of lung volume in the cuffed TT group and reduction of lung volume in the uncuffed TT group, with likely associated changes in lung compliance, functional residual capacity (FRC) and ventilation.

Additionally, and in line with previous findings [1, 2], cuffed TTs were associated with greater ease of insertion, lower leak/tidal volume ratio, fewer postoperative complaints and fewer adverse events. The decreased incidence of sore throat and hoarse voice in the cuffed TT group may reflect decreased requirement for repeated airway instrumentation.

Subanalysis of the effect of neuromuscular blockade on leakage was not possible, due to the low numbers involved (and therefore insufficient power). However, usage of neuromuscular blockade was similar between tube type and age groups, and an exploratory analysis (data not presented) did not suggest any impact of neuromuscular blockade on the results studied.

Advantages of the use of cuffed TT are reported as being a reduced need for multiple intubation attempts to correctly size a tube [1]; lower atmospheric pollution [6, 8] due to lack of a leak; more reliable capnography [1]; lower risk of micro-aspiration [9]; decreased sore throat [2]; lower risk of airway fires during oropharyngeal procedures [10]; and economic benefits of lower gas and anaesthetic use [11, 12]. In a retrospective study, Mahmoud demonstrated that tracheal tube leak of > 5% tidal volume was present in 75% of infants ventilated in neonatal intensive care with uncuffed TTs, and the leak was up to 40% tidal volume in > 40% of infants [13]. These findings are consistent with the results of our study, which showed a leak/tidal ratio of 32% in the < 6 years and 39% in 6–16 years groups. Fine et al. showed similar results (31% leak/tidal volume ratio) in infants whose lungs were ventilated [11]. Main et al. suggested in their study [14] that a tube leak of > 20% is associated with an inconsistent tidal volume, and overestimation of lung compliance and resistance which can lead to impaired ventilation. Consequences of suboptimal lung monitoring may include avoidable atelectasis, loss of volume or unnecessary shearing forces, thus increasing the risk of ventilator-induced lung damage. Without accurate tidal volume monitoring, lung protective strategies become difficult. It is suggested that a cyclical process of recruitment and atelectasis may contribute to lung inflammation [15]. However, evidence is lacking about whether there are advantages from ventilation with cuffed TT in children due to leak minimisation.

There is a financial cost associated with cuffed TTs, which are generally more expensive than uncuffed tubes, but this is offset by a lower incidence of tube changes (i.e. cost of tubes and the time required for tube change) and lower fresh gas use [12].

Our study has some limitations. These include the use of four different types of available cuffed TT. There are numerous manufacturers of TTs, each having a different outer diameter and cuff qualities, but our results only reflect the four cuffed TT types in use at our institution. The ultimate choice of TT size was made by the attending anaesthetist, which introduced another element of variability. Also, there was no standardisation of the anaesthetic drugs used, but all were administered according to routine practice in our institution. The use of neuromuscular blockade was inconsistent, and could potentially be a confounding variable affecting both leak and tidal volume. Different ventilation modes or settings may have changed our results. There may also have been some error in the calculations of tidal volumes and tube leak by the Dräger Primus Anaesthesia Machine, but this would have affected both groups equally. Finally, we did not distinguish between leak during inspiration and expiration, and assumed that most of the leak occurred during inspiration because of larger pressure gradients. Expired tidal volume might not therefore be an accurate indicator of changes in lung volume because expiratory leak has not been measured or taken into account. Any expired leak could thus be associated with an overestimate of lung volume loss.

Trials examining various pressures in supraglottic airway devices have demonstrated that lower cuff pressures produce a lower incidence of sore throat [16]. To date, there are no prospective randomised trials that compare the rate of sore throat with cuffed and uncuffed TT, but an audit at our own institution [2] showed a higher incidence of sore throat in children receiving an uncuffed TT, and the incidence of sore

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throat in those with cuffed TT positively correlated with cuff pressure.

Under standardised ventilation settings, cuffed TTs were associated with lower leak, higher tidal volumes and more stable ventilation parameters. Additionally, children intubated with cuffed TT showed less adverse events, sore throat and hoarse voice. The results of this randomised controlled trial add to the growing body of evidence that cuffed TTs may be associated with superior outcomes when compared with uncuffed TTs in children.

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